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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,354	12/22/2004	Robert J. Hariri	9516-059-999	6502

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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	**PAPER NUMBER**
1643	
MAIL DATE	**DELIVERY MODE**
08/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,354	HARIRI ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 25-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13 and 25-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-13 and 25-36 are all the pending claims for this 371 application and subject to lack of unity restriction/election of species requirement.

2. Applicants' Reply of 6/18/07 to the Office Action of 5/16/07 is acknowledged. In the Reply, Applicants cancelled Claims 14-24, which were restricted to Group II based on the Examiner's finding for lack of unity of invention over the subject matter disclosed in Lyden et al. (Nature Medicine (Nov. 2001) 7:1194-1201) and Mesters et al. (Blood (July 2001) 98(1):241-243). Thus pending Claims 1-13 are all the original claims of original Group I. New Claims 25-36 were added in the Reply and all of which depend from Claim 1. However, the new claims, specifically new claims 31, 32 and 36, add newly restrictable subject matter as discussed in the telephone interview with Applicant's representative, Lawrence Graham, on 8/22/07. A deadline for response to the telephone election of species for cancer cells (Claims 31 and 32) and stimulator of angiogenesis (Claim 36) was set for noon on 8/24/07. In the absence of a timely response, the instant Office Action is herein issued and effectively vacates the Office Action of 5/16/07.

Election of Species

3. This application contains claims directed to the following patentably distinct species (stem cell culture conditions) of the claimed invention:

a. hydrocortisone

b. epidermal growth factor

c. bovine brain extract

The species of component for the stem cell culture condition are structurally and functionally different molecules. For example, hydrocortisone is a steroid, epidermal growth factor is a protein growth factor and bovine brain extract contains an undefined, complex mixture of hormones, proteins, fatty acids, etc. It is expected that each of the species would effect stem cell differentiation through different signaling pathways with each having a different end result on stem cell differentiation. Therefore, the species are patentably distinct.

If Applicant elects Invention of Group I, Applicant is required under 35 U.S.C. 121 to further elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-4, 6-13 and 25-36 are generic.

4. This application contains claims directed to the following patentably distinct species (tumor cells) of the claimed invention:

a) HTB-104 cells

b) CRL-1973 cells

c) BT483 cells

d) Hs578T cells

e) HTB2 cells

f) BT20 cells

g) T47D cells

The species of tumor cell are structurally and functionally different cell types. In the instant case the species of cancer can originate from any number of different cell types (e.g., epithelial, mesothelial or endothelial) and are expected to be under the influence of different growth factors, hormones, cytokines, etc. For example HTB-104 cells are an embryonal carcinoma of the testes, CRL-1973 cells are a malignant pluripotent embryonal carcinoma of the testes, BT483 cells are a mammary gland ductal carcinoma, Hs578T cells are mammary gland carcinoma, HTB2 cells are a human mammary carcinoma expressing HER2, BT20 cells are a mammary adenocarcinoma (isolated from a primary invasive ductal carcinoma; express E-cadherin, ER, EGFR and uPA), and T47D cells are an estrogen receptor negative breast cancer. It is not expected that each of the species would express the same cellular or soluble markers or secrete the same soluble factors under the assay conditions for the method.

Applicant is required under 35 U.S.C. 121 to further elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-13, 25-30 and 33-36 are generic.

5. This application contains claims directed to the following patentably distinct species (stimulator of angiogenesis) of the claimed invention:

acidic fibroblast growth factor (aFGF), angiogenin, basic fibroblast growth factor (bFGF), epidermal growth factor, granulocyte colony stimulating factor (GCSF), interleukin 8 (IL-8), placental growth factos (PGF), platelet-derived growth factor

(PDGF), scatter factor (hepatocyte growth factor), transforming growth factor alpha (TGF~t), tumor necrosis factor alpha (TNFa), vascular endothelial growth factor (VEGF), adenosine, 1-butyryl glycerol, nicotinamide, prostaglandin E 1 or prostaglandin E2.

The species of angiogenesis stimulator do not share a common core structure or function, thus the species are patentably distinct. One of ordinary skill in the art could readily consult any reference manual (e.g., Merck Index, Physician's Desk Reference, the Red Book, Goodman & Gillman), the U.S. Pharmacopeia (USP.org) or any commercial protein database (e.g. SwissProt) describing the structure, solubility characteristics, biological properties and/or contraindications for each of the species, and would appreciate that based on these reference disclosures alone or in combination, that these species are distinct and separate. Each of the species promotes its effect through different signaling pathways by way of a different receptors. It is not expected that each of the species would equally effect just any stem cell under the assay conditions for the method.

Applicant is required under 35 U.S.C. 121 to further elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-13 and 25-35 are generic.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER